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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,812	07/10/2001	Diane Pennica	GENENT.083A	7879

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,812	PENNICA ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8-10 and 67-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8-10 and 67-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 26, 2004 is acknowledged and has been entered. Claims 2, 6-7, and 11-66 have been canceled. Claims 3-5 and 10 have been amended. Claims 67-80 have been added.

2. Claims 1, 3-5, 8-10, and 67-80 are pending in the application and currently under prosecution.

Priority

3. In reply to the previous Office action, Applicant has stated that US Patent Application No. 09/759,056 was filed January 11, 2001, rather than January 21, 2001, as the first page of the instant specification incorrectly indicates. Because US Patent Application No. 09/759,056 was filed January 11, 2001, rather than January 21, 2001, it properly claims benefit of the earlier filing date of US Provisional Application No. 60/175,849 filed January 13, 2000.

Applicant is required to correct the apparent typographical error by amending the first paragraph of the specification appropriately.

The earliest effective filing date of this application is determined to be the filing date of US Provisional Application No. 60/175,849 filed January 13, 2000.

Declaration

4. Receipt of the new declaration filed August 20, 2004 is acknowledged; however, the new declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration filed August 20, 2004 is defective because: An executed copy of the declaration by Inventor Paul Polakis has not been received.

Specification

5. As set forth in the previous Office action, the specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Although Applicant has attempted to resolve this issue by amending the specification appropriately, additional examples of improperly demarcated trademarks still occur, including Taxol™ (page 20, line 4), Qiagen™ RNeasy™ (page 24, line 30), and Lightcycler™ (page 25, line 36).

Appropriate corrections are required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Rejections – 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3-5, 8-10, and 67-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reason set forth in section 10 of the previous Office action mailed April 24, 2004.

At page 14-16 of the amendment filed July 26, 204, Applicant has traversed this ground of rejection, arguing, in brief, that the written description requirement is satisfied because extensive guidance is provided in the specification for one skilled in the art to identify tumor cells characterized by aberrant Wnt signaling, one skilled in the art knows that genetic defects and/or altered expression patterns of a member of a signaling pathway will cause aberrant signaling by the pathway, and the present knowledge in the art, together with the instant description of multiple species of tumor cells characterized by aberrant Wnt signaling, provide adequate written description of the genus of such tumors cells.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

As noted in the previous Office action, the specification defines the term "characterized by aberrant Wnt signaling" as including "genetic defects and/or altered expression patterns (including mutations, amplification, over-expression and/or suppression) of any of these members of the Wnt signaling pathway, or any other members, known today **or hereinafter identified**" (emphasis added) (lines 9-11). Accordingly, the claims encompass a method comprising treating a tumor cell characterized as having genetic defects and/or altered expression patterns, including mutations, amplification, over-expression, and/or suppression of any known, *or yet to be discovered* member of a genus of proteins involved in a Wnt signaling pathway.

Thus, contrary to Applicant's assertion that the Examiner has not met its initial burden of presenting a preponderance of evidence why a skilled artisan would not recognize in Applicant's disclosure a description of the invention defined by the claims, the previous Office action states succinctly why the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed: one cannot describe what has not been discovered, isolated, and/or characterized; and therefore the instant written description of the claimed invention cannot suffice to meet the requirements set forth under 35 USC § 112, first paragraph.

Moreover, as the disclosed or known members of the Wnt signaling pathway are disparate in structure and function, the skilled artisan cannot envision, or even predict the structure of any hereinafter identified members of Wnt signaling pathway. As members of the Wnt signaling pathway have yet to be discovered, the members of the genus of tumor cells having aberrant Wnt signaling cannot be recognized or distinguished from others.

Applicant has argued that given the present knowledge in the art regarding the Wnt signaling pathway, the instant description of multiple species of tumors cells characterized by aberrant Wnt signaling would reasonably convey that Applicant had possession of the claimed invention at the time the application was filed. However, as noted previously, since the members of the genus are so variant in structure and function, the instant description of some species of tumor cells characterized by aberrant Wnt signaling cannot suffice to describe the genus as a whole, because, even given benefit of the instant disclosure of the claimed invention, the skilled artisan could not instantly envision, recognize, or distinguish at least a substantial number of the members of the genus. The examples described are not representative of the genus as a whole, since, for example, the genus includes members characterized by defects or abnormal levels of expression of signaling molecules, which have yet to be discovered, isolated, or described.

Furthermore, apart from the tumor cells described in the specification as having aberrant Wnt signaling, the skilled artisan cannot envision or predict the nature of the genetic defects and/or altered expression patterns, including mutations, amplification, over-expression, and/or suppression of the known members of the Wnt signaling pathway, so as to immediately recognize any other tumor cells having aberrant Wnt signaling.

Applicant has argued that one skilled in the art knows that genetic defects and/or altered expression patterns of a member of a signaling pathway will cause aberrant signaling by the pathway; while this is generally true, provided the members of a signaling pathway are known and their function in the pathway has been well characterized, if a member of any given signaling pathway has yet to be described, the

skilled artisan cannot know its role in the pathway and cannot know that genetic defects or its altered expression will cause aberrant signaling by the pathway.

Claim 74-80 are more narrowly directed to a genus of tumor cells characterized by aberrant Wnt signaling of a member of the Wnt signaling pathway selected from the group consisting of Wnt gene family members, APC, catenin, members of the family of frizzled receptors, disheveled protein, glycogen synthase kinase-3β, transcription factor TCF/LEF-1, nodal related 3 gene, Xnr3, members of the homeobox gene family, members of the engrailed gene family, goosecoid, twin (Xtwn), siamois, c-myc, and the members of the WISP genes. However, the specification would not reasonably convey that Applicant had possession of the claimed invention because, even given the description of the claimed invention set forth in the instant disclosure, the skilled artisan could not immediately envision, recognize, or distinguish members of the genus of tumor cells characterized by defects in, or abnormal expression levels of any of these genes or gene products, since, for example, many have yet to be discovered, isolated, or described. Notably, claims 74-80 are not limited to tumor cells characterized by aberrant Wnt signaling caused by defects in the expression or activity of readily known and well-characterized members of the Wnt signaling pathway.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4, 69, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reason set forth in section 12 of the previous Office action mailed April 24, 2004.

At page 16 of the amendment filed July 26, 2004, Applicant has traversed this ground of rejection, arguing that the metes and bounds of the subject matter that Applicant regards as the invention can be unambiguously determined by the skilled artisan, since the phrase "corresponding normal cells" is used throughout the specification and therefore the skilled artisan would understand that the normal cells to

which the claims are directed must correspond to the tumor cells in tissue type. For example, Applicant has asserted that the skilled artisan would understand that, were the tumor cells of colon cell origin, the corresponding normal cells would be normal, non-tumor cells of the colon.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Limitations cannot be read into the claims. If Applicant regards their invention as a method for enhancing the expression of a protein in a tumor cell, where the protein is overexpressed in tumor cells, as compared to normal cells of the tissue type from the tumor cells originated, then, Applicant should amend the claims appropriately to particularly point out and distinctly claim that invention. Contrary to Applicant's assertions, the skilled artisan would not understand that Applicant regards such subject matter as their invention, because the specification does not clearly define the "corresponding normal cells" as cells of the same tissue type from which the tumor cells arose; and the "corresponding normal cells" could otherwise be regarded as normal cells of the same cell type (e.g., epithelial, endothelial, etc.) as the tumor cells, rather than of the same tissue type.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 3-5, 8-10, and 67-80 are rejected under 35 U.S.C. 102(a) as being anticipated by Chu et al. (*J. Nutr.* **129**: 1846-1854, 1999), as evidenced by Pennica et al. (*Proc. Natl. Acad. Sci. USA.* **95**: 14717-14722, 1998) and Szeto et al. (*Cancer Res.* **61**: 4197-4205, 2001; cited by Applicant) for essentially the reason set forth in section 14 of the previous Office action mailed April 24, 2004.

At pages 17 and 18 of the amendment filed July 26, 2004, Applicant has traversed this ground of rejection, arguing that the Szeto et al. is not properly considered prior art (page 17, paragraph 3) and Chu et al. does not anticipate the claimed invention, because Chu et al. does not treating cancer cells characterized by aberrant Wnt signaling with retinoic acid (paragraph bridging pages 17 and 18). Furthermore, Applicant has asserted that Chu et al. does not anticipate the claimed invention because Chu et al. does not teach the expression of Stra6 is characterized by synergistic enhancement of expression by a combination of Wnt and the retinoid (page 18, paragraph 1).

In addition, Applicant has argued that Pennica et al. does not teach selective enhancement of expression of a protein in a tumor cell characterized by aberrant Wnt signaling comprising treating said tumor cells with a retinoid, since Pennica et al. only teaches cloning genes induced in "Wnt-1 transformed cells" (Applicant's amendment, page 18, paragraph 2).

Furthermore, on the basis that "the only cell line in common between the Chu et al. and Pennica et al. papers is HT-29", because Chu et al. discloses that HT-29 colon cancer cells are retinoic acid-resistant, Applicant has argued that Pennica et al. does not anticipate the claimed invention (Applicant's amendment, page 18, paragraph 2).

Applicant's arguments have been carefully considered but have not been found persuasive for the following reasons:

As an initial matter, it is noted that Applicant has remarked that Szeto et al. is not prior art. Agreeably, Szeto et al. is not prior art; however, both Szeto et al. and Pennica et al. are evidentiary, cited to show a characteristic of the cancer cells treated with retinoic acid (RA), which is not disclosed by Chu et al., is inherent. See MPEP § 2131.01. Accordingly, in reply to Applicant's argument that Pennica et al. does not teach selective enhancement of expression of a protein in a tumor cell characterized by aberrant Wnt signaling comprising treating said tumor cells with a retinoid, since Pennica et al. only teaches cloning genes induced in "Wnt-1 transformed cells", Pennica et al. is cited as evidence that the cancer cells treated by Chu et al. are, as a matter of inherency, characterized by aberrant Wnt signaling. In reply to Applicant's argument

that, because Chu et al. discloses that HT-29 colon cancer cells are retinoic acid-resistant, Pennica et al. does not anticipate the claimed invention, again, Pennica et al. is cited as an evidentiary reference only; it is not used, nor it is intended to be used as an anticipatory reference under 35 USC § 102. In addition, it is aptly noted that Chu et al. teaches HT-29 cells are RA-*resistant*, not non-responsive, and this difference is significant. Although Chu et al. teaches treating HT-29 cells with RA did not induce the expression of *Gpx1,* Chu et al. shows the treatment did induce expression of Gpx2 (page 1851, Table 2); and it further noted that it has been reported by others that HT-29 cells are responsive to RA, as gene expression in these cells was altered upon treatment of the cells with the retinoid. Notably, Chu et al. does not teach that RA does *not* induce expression of the gene encoding Stra6 in HT-29 cells.

Claims 1, 3-5, 8-10, and 67-80 are drawn to a method comprising treating a colon or breast tumor cell characterized by aberrant Wnt signaling caused by genetic defects and/or altered expression patterns, including mutations, amplification, over-expression and/or suppression, of members of the Wnt signaling pathway, including the *WISP*, *APC*, and *β-catenin* genes, with an effective amount of RA to selectively enhance the expression of Stra6 in the cell.

Chu et al. teaches treating colon and breast tumor cells with an effective amount of RA to affect gene expression in those cells (page 1649, column 2, through page 1851, column 1; and page 1851, Table 2).

Chu et al. does not expressly teach that the tumor cells treated with RA are characterized by aberrant Wnt signaling, caused in particular by mutations in the *WISP*, *APC*, or *β-catenin* genes. Nevertheless, as evidenced by Pennica et al., at least breast and colon cancer cells are characterized by aberrant Wnt signaling, since Pennica et al. teaches colon cancer cell lines showed significant (2- to 4-fold) amplification of the gene encoding WISP-1 (page 14720, column 2 and Figure 5). As expected of amplified genes, Pennica et al. teaches the *WISP* genes are over-expressed in clinical specimens of colon adenocarcinoma (page 14720, column 2, through page 14721, column 1; page 14721, Figures 6 and 7). Furthermore, Pennica et al. teaches breast and colon tumor

cells had been previously characterized by mutations in other genes, which aberrantly affect Wnt signaling. For example, Pennica et al. teaches colon carcinomas had been characterized by mutations in either APC or β-catenin (page 14717, column 2). Additionally, Pennica et al. discloses virus-induced breast cancer had been characterized as aberrantly expressing *Wnt-1*, which is not normally expressed in breast tissue (page 14717, column 1). Pennica et al. teaches that when *Wnt-1* is aberrantly expressed in breast and colon cells, it causes their transformation (page 14717, column 1 and column 2).

The specification lists members of the Wnt signaling pathway, including APC, β-catenin, and the *WISP* genes (e.g., *WISP-1* and *WISP-2*) (page 13, line 34; and page 14, lines 4-8), and defines the term "characterized by aberrant Wnt signaling" as including "genetic defects and/or altered expression patterns (including mutations, amplification, over-expression and/or suppression) of any of these members of the Wnt signaling pathway, or any other members, known today or hereinafter identified" (lines 9-11). Accordingly, the claims are drawn to a method comprising treating a colon or breast tumor cell characterized by genetic defects and/or altered expression patterns, including mutations, amplification, over-expression and/or suppression, with an effective amount of retinoic acid to selectively enhance the expression of Stra6 in the cell. Chu et al. teaches treating colon and breast cancer cells with an effective amount of retinoic acid to affect the expression of genes in the cells, which, as evidenced by Pennica et al., are characterized by mutation, amplification, and/or over-expression of a gene encoding a member of the Wnt signaling pathway, such as APC, β-catenin, and WISP.

Although Chu et al. does not expressly disclose that treating breast and colon cancer cells characterized by aberrant Wnt signaling with RA induces the expression of *Stra6*, as evidenced by Szeto et al., the gene encoding Stra6 is RA-responsive in human cancers, i.e., its expression is induced by treatment of the cells with RA. Szeto et al. discloses that it had been previously shown by Bouillet et al., which is cited by Szeto et al. as reference 35, that treating cancer cells with RA induced the expression

of Stra6 (page 4197, column 2); and accordingly, Szeto et al. discloses *Stra6* was "known to be up-regulated by retinoic acid" (abstract).

Chu et al. does not expressly disclose that RA synergistically enhances the expression of Stra6 in concert with the expression of Wnt-1 in cancer cells. Nevertheless, Szeto et al. teaches that the stimulation of cancer cells characterized by aberrant Wnt signaling with RA in the presence of Wnt-1 induced a level of Stra6 in the cells that greatly exceeded that observed with either stimulus alone (abstract).

MPEP § 2112 [R-2] states:

> The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

The purpose of treating the tumor cells with retinoic acid, as disclosed by Chu et al., is to achieve a method of inducing gene expression in those cells. Chu et al. does not expressly disclose that retinoic acid possesses *Stra6*-inducing activity; nor does Chu et al. expressly disclose treating a breast or colon tumor cell characterized by aberrant Wnt signaling with retinoic acid to achieve a method for the selective enhancement of the expression of Stra6 in those cells. Nevertheless, retinoic acid inherently possesses *Stra6*-inducing activity and the prior art's step of treating a breast or colon tumor cell characterized by aberrant Wnt signaling with retinoic acid inherently and necessarily constitutes a method for a method for the selective enhancement of the expression of Stra6 in those cells. See *Ex parte Novitski*, 26 USPQ2d 1389 (BPAI 1993). See MPEP §§ 2112 [R-2] and 2112.02 [R-2].

Moreover, Chu et al. treated the breast and colon cancer cells with RA, intending to characterize the affect of the treatment upon gene expression in the cells.

"Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent". *Bristol-Myers Squibb Company v. Ben Venue Laboratories*, 58 USPQ2d 1508, 1514 (CAFC 2001).

Although Chu et al. does not expressly disclose that, as a result of treating the cells with RA, the gene encoding Stra6 is induced, the process necessarily produced those results, since, as evidenced by Pennica et al. *Stra6* is RA-responsive.

As to inherency, the Court has noted that "[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Mehl/Biophile Int'l Corp. v. Miligraum*, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted). Moreover, "[w]here [...] the result is necessary consequence of what was deliberately intended, it is no import that the article's authors did not appreciate the results." *Mehl/Biophile Int'l Corp*, 192 F.2d 1362, 52 USPQ2d at 1307.

Therefore, in further reply to Applicant's argument that Chu et al. does not anticipate the claimed invention because Chu et al. does not teach the expression of Stra6 is characterized by synergistic enhancement of expression by a combination of Wnt and the retinoid, mere recognition of latent properties in the prior art does not render nonobvious, or cause a failure to anticipate a claimed invention, where otherwise the invention is known. See *In re Wiseman,* 201 USPQ 658 (CCPA 1979).

Furthermore, granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. See *In re Baxter Travenol Labs,* 21 USPQ2d 1281 (Fed. Cir. 1991). See MPEP § 2145. The Court of Appeals for the Federal Circuit has stated that "[I]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable" See *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1575, 1936 (Fed. Cir. 1990) (emphasis in original).

In summary, because RA was previously known to induce Stra6 in human cancer cells, as evidenced by Szeto et al., and because, as also evidenced by Szeto et al., RA synergistically enhances the expression of Stra6 in concert with the expression of Wnt-1 in cancer cells, since Chu et al. teaches treating cancer cells, which as evidenced by Pennica et al. are characterized by aberrant Wnt signaling, with RA, the process disclosed by Chu et al. inherently and necessarily constitutes a method for selectively

enhancing the expression of Stra6 in those cells. Moreover, because Chu et al. discloses the amount of RA used to treat the cells was effective to affect gene expression in the cells, absent a showing of any difference, the method of the prior art is deemed the same as the claimed method. The Office, however, does not have the facilities for examining and comparing Applicant's claimed process with the process disclosed by the prior art in order to establish that the process of the prior art does not produce the same results as the claimed invention. In the absence of evidence to the contrary, the burden is upon the Applicant to prove that the claimed process is different than that taught by the prior art.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 14, 2004

Jeffrey Siew
JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
10/16/04